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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/056,806	04/08/98	VERMEULEN A	I/97272

HM12/0625

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EXAMINER	
WEATHERSPOON, J	
ART UNIT	**PAPER NUMBER**
1645	3

DATE MAILED: 06/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/056,806	Vermeulen et al
Examiner	**Group Art Unit**
John K. Weatherspoon	1645

☒ Responsive to communication(s) filed on *Apr 8, 1998*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-15, 18, 19, and 21-32* is/are pending in the application.

Of the above, claim(s) *6-11, 18, 21-26, 29, and 31* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5, 12-15, 19, 27, 28, 30, and 32* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 12-15, 19, 27-28, 30 and 32, drawn to composition free of whole Eimeria parasites which comprises proteins, vaccine composition comprising said composition free of whole Eimeria parasites, immunological reagent and test kit comprising said immunological reagent, classified in class 424, subclass 184.1.

II. Claims 6-11, 13-14, 21-28 and 31, drawn to isolated nucleic acid molecule, vector, host comprising said vector, vaccine composition comprising said vector and test kit comprising said nucleic acid molecule, classified in class 536, subclass 23.1.

III. Claims 18 and 29, drawn to antibody or derivative thereof and test kit comprising said antibody or derivative thereof, classified in class 530, subclass 387.1.

2. The inventions are distinct, each from the other because of the following reasons:

The claims of Groups I-III are drawn to structurally and functionally distinct products. Group I contains claims drawn to composition which comprises proteins. Group II contains claims drawn to isolated nucleic acid molecule. Group III contains claims drawn to antibody. The proteins of Group I comprise amino acids whereas the nucleic acid of Group II comprises nucleotides. The antibody of Group III comprises Fab and Fc portions whereas the proteins of Group I do not. These products are clearly distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and/or recognized divergent subject matter and because the searches required for examination of the groups identified above are not coextensive, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mary Gormley on June 7, 1999, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-5, 12-15, 19, 27-28, 30 and 32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-11, 18, 21-26, 29 and 31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

NO 3. If applicant desires priority under 35 U.S.C. 119 based upon previously filed foreign application 97302447.4 filed 9/4/97, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

5. This application has been filed with informal drawings which are acceptable for examination purposes only. The drawings are objected to by the draftsperson under 37 C.F.R. 1.84 or 1.152. See PTO-948 for details. Correction of the noted defects can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 12-15, 19, 27-28, 30 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to

make and/or use the invention. The claimed invention is drawn to drawn to a composition free of whole Eimeria parasites which comprises one or more proteins or variants thereof, a vaccine composition comprising said composition free of whole Eimeria parasites, and an immunological reagent comprising a protein or variant thereof. For the reasons discussed below, one skilled in the art recognizes that variants of proteins are unpredictable with regard to biological function, e.g. as protein variants in vaccine compositions, wherein vaccines are intended to stimulate immune response, and wherein "variants" encompass proteins with amino acid substitutions, deletions and/or additions. Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (see Burgess et al.). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduce the biological activity of the mitogen (see Lazar et al.). These references demonstrate that a even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. The specification does not support the broad scope of the claims which encompass a multitude of analogs or equivalents because the specification does not disclose the general tolerance to modification and extent of such tolerance; specific positions which can be predictably modified; and the specification provides essentially no guidance as to which of the essentially infinite possible choices is likely to be successful.

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the myriad of derivatives and variants encompassed in the scope of the claims one skilled in the art would be forced into undue experimentation in order to practice broadly the claimed invention. Applicants have not provided sufficient guidance to enable one skilled in the art to make and use the cliamed derivatives in a manner reasonably correlated with the scope of the claims broadly including nay number of deletions, additions and/or substitutions of any size. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 12-15, 19, 27-28, 30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "Triton X-114" and "SDS-PAGE" in said claims are indefinite since one skilled in the art would not be apprised of the exact identity/composition of said terms; and absent recitation of the exact composition of "Triton X-114" and "SDS-PAGE", said terms render the claims indefinite. Since the specification does not

provide a standard for ascertaining the exact identity/ composition of these terms, one skilled in the art would not be reasonably apprised of the scope of the invention.

M 8. Claim 14 and dependent claims thereof, i.e. claim 28, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "Quil A" in said claims is indefinite since one skilled in the art would not be apprised of the exact identity/composition of said term; and absent recitation of the exact composition of "Quil A", said term renders the claims indefinite. Since the specification does not provide a standard for ascertaining the exact identity/ composition of "Quil A", one skilled in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-5, 12-15, 19, 27-28, 30 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Vermeulen et al (effective filing date 6/18/92; see PTO-892). Vermeulen et al disclose an Eimeria protein with a disclosed molecular weight of "about 20kDa" (see entire reference) or functional fragments or variants thereof (e.g. see column 5 of reference), i.e. which

encompasses an Eimeria protein of molecular weight of atleast 19-21 kDa, wherein said protein has antigenic/immunogenic properties and wherein said "about 20kDa" protein can be used to prepare vaccine composition for administration to protect against coccidiosis (see entire reference). Vermeulen et al further disclose that said protein is "essentially free from the whole parasite or other protein", and said protein can be used for vaccine preparation. Vermeulen et al further disclose that said protein is present in the hydrophilic phase of a Triton X-114 extract of Eimeria sporozoites, specifically from extract of Eimeria acervulina sporozoites. Vermeulen et al further disclose that said vaccine composition comprising said protein can further comprise pharmaceutically acceptable carrier, the adjuvant Quil A, and wherein said vaccine composition is in unit dosage form (see entire reference). In view of said disclosure all limitations of said claims are anticipated by the prior art.

Status of Claims

10. No claim is allowed.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1645 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Weatherspoon, Ph.D. whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (703) 308-3995.

John Weatherspoon, Ph.D.

June 17, 1999

Anthony Caputa, Ph.D.

Supervisory Primary Examiner

Group 1645